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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 2787 10/079,954 02/19/2002 Matthias Durst SCHU-204.1 EXAMINER 09/13/2004 Fulbright & Jaworski LLP CANELLA, KAREN A 666 Fifth Avenue PAPER NUMBER ART UNIT New York, NY 10103 1642

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		[ A _ 1' _ 4/ \
	Application No.	Applicant(s)
	10/079,954	DURST ET AL.
Office Action Summary	Examiner	Art Unit
	Karen A Canella	1642
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on		
2a) This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>1,2 and 22-50</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) 1.2.22-50 are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment/s\		
Attachment(s)  1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summar	v (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	Date
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date	5) Notice of Informal 6) Other:	Patent Application (PTO-152)

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## **DETAILED ACTION**

1. Claims 3-21 have been canceled. Claims 22-50 have been added. Claims 1, 2 and 22-50 are pending.

## Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 and 2, drawn to nucleic acids suitable for evaluating the progression of a potential cervical lesion, classified in class 536, subclass 23.5.
  - II. Claims 22-37, drawn to methods for diagnosing cervical lesions and evaluating the progression potential of a cervical lesion comprising determining the presence or absence of peptides in a sample and a method for the diagnosis of a cervical lesion comprising determining the presence or absence of auto-antibodies directed against peptides, classified in class 435, subclass 7.1.
  - III. Claims 39-45, drawn to an isolated polypeptide characterized for early or late passage of HPV immortalized cells and isolated polypeptides comprising SEQ ID NO:1, classified in class 530, subclass 300 and 350.
  - IV. Claims 38 and 46-50, drawn to a kit for carrying out the method of claim 22 and antibodies and antibody fragments which bind to the polypeptides of claim 29, classified in class 530, subclass 387.1. Claim 38 is examined with this group to the extent that it reads on a kit comprising and antibody.
- 3. The inventions are distinct, each from the other because of the following reasons:
- 4. Inventions of Groups I, III and IV are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.
- 5. Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group IV can be used in a method to raise an anti-idiotypic antibody in an experimental animal.

- 6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.
- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen A. Canella, Ph.D.

9/9/2004

MARIN A. CANELLA PH.D.

DELMARY EXAMINER

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